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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,856	03/05/2002	Mark S. Leung	12361-8US	8363

20988 7590 07/11/2003
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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,856

Applicant(s)

LEUNG ET AL.

Examiner

Aaron Roane

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-- **Th MAILING DATE f this c mmunication appears on the cover sheet with th correspondence address --**
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-18 is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 8 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 1-13 are objected to because of the following informalities: The claimed invention is directed to a “device for treatment of a patient’s intervertebral disc”. However, the invention is more appropriately characterized as a system than a device. Therefore, the examiner suggests the following to claim 1. The word “device” should be changed to –system--.

Accordingly, the preambles of claims 2-13 should also be changed such that the word “device” is changed to –system--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Regarding claims 3 and 4, both claims 3 and 4 further limit the energy delivered in the form of electrical current. Both claims 3 and 4 are dependent

upon claim 2. However, claim 2 does not positively recite energy in the form electrical current. Claim 2 recites that the form of energy is selected from the group of electrical current; microwave; ultrasound; and thermal energy. In order for claims 3 and 4 to be definite, a positive recitation of the form of energy being electrical current (only) in the preceding dependent claim (claim 2) is required.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Regarding claim 14, it is unclear whether Applicant means surface or ends when Applicant refers to “inner end” and “outer end”. If applicant is indeed referring to “ends”, then —distal— and —proximal— would be clearer than “inner” and “outer”. However, if Applicant is referring to surfaces, than “inner” and “outer” are sufficient. For the purposes of an initial examination, the examiner interprets “inner end” and “outer end” to mean distal end and proximal end respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 9, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fletcher et al. (USPN 5,591,162).

Regarding claim 1, Fletcher et al. disclose a system comprising a first and second elongate probe (both denoted as 8, see figure 11), wherein the distal portion of each probe comprises energy delivery means (distal end of 8 denoted as “tumor heating section” in figure 2), see col. 3 and 4 and figures 1, 2 and 9-13.

Regarding claim 2, Fletcher et al. further disclose that the form of energy is thermal energy, see col. 3 and 4.

Regarding claims 5 and 6, Fletcher et al. further disclose a system capable of performing the recited functions (temperature control), see col. 3 and 4. Note that Fletcher et al. further disclose a temperature control means (15). The recitations containing the phrase “adapted to” is intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

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order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 9, Fletcher et al. further disclose a cooling means (not shown), see starting on col. 4, line 3 and ending on col. 5, line 4.

Regarding claim 10, Fletcher et al. further disclose an external elongate portion of at least one probe that includes an electrically insulated sleeve (30), see starting on col. 5, line 59 and ending on col. 6, line 11 and figures 5 and 5B.

Regarding claim 13, Fletcher et al. further disclose a distal portion having a shape for directing the delivery of thermal energy into the tissue and tumor, figures 1, 2, 5 and 10.

Claims 1-7, 10, 12-14, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggers et al. (USPN 5,928,159).

Regarding claims 1-4 and 19, Eggers et al. disclose a system (100) for treating tumors comprising a first and second elongate probe (110), wherein the distal end of the probe comprises a energy delivery means (electrodes on 113), see col. 7, lines 18-67 and figure 5. The energy delivered by the energy delivery means is in the form of radio frequency electrical current with a frequency of 20 kHz to 20 MHz, see col. 5, lines 58-67.

Regarding claims 5 and 6, Eggers et al. further disclose a system capable of performing the recited temperature and heating functions. The recitations containing the phrase “adapted to” is intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claims 7 and 20, Eggers et al. further disclose a system comprising an electrical impedance meter (measurement means) communicating between the distal portions of each probe, see col. 7, lines 36-56 and figure 5.

Regarding claim 10, Eggers et al. further disclose a system comprising an external elongate portion of at least one probe including an electrically insulated sleeve, see col. 4, lines 53-65 and figures 2 and 3.

Regarding claims 12-14, Eggers et al. further disclose at least one hollow tubular probe (the probes are identical) with a temperature sensor at the distal end, see col. 7, lines 8-18. Additionally, the shape of the probes is inherently configured to direct energy. In this case the cylindrical shape of the probes substantially directs energy away from the probes longitudinal axis, see figures 4 and 6.

Allowable Subject Matter

Claims 15-18 are allowed.

Claims 8 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Many of the Sharkey et al. and Sluijter et al. references could have been used to reject claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. *A.R.*
July 2, 2003

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER